

REMARKS

I. STATUS OF THE APPLICATION

Claims 1 – 26 were filed in the original application. In response to the Restriction Requirement in the Office Action mailed April 10, 2006, Applicants cancelled claims 1 – 26, 30, and 39 – 49, and added claims 50 – 87. In a previous amendment, Applicants cancelled claims 36, 61, 72 and 79. In the present amendment, all remaining claims from 1-87 are cancelled and new claims 88-206 are added.

Applicants note that the priority claim has been amended. As amended, the earliest priority date of March 2, 2001 is now derived from U.S. patent application serial number 09/798,007.

Applicants submit that the provision of the new claims does not add new matter to the application. Support for the new claims can be found, for example, in the portions of the specification describing triangulation methods. Exemplary description is found at page 20, line 30 to page 21, line 20 and in Figures 14-17 and the text and experimental work related to Figures 14-17. A description of triangulation methods is found in the March 2, 2001 prior document at, for example, the paragraph spanning pages 27-28. Support is also found in the priority document, for example, in the text spanning pages 13-14. Support for the genes of claims 118, 146, 177, and 206 is found, for example, in Table 8, beginning on page 49, and Table 11, on page 58 of the specification.

There are three rejections in the Office Action of October 17, 2007. The currently pending rejections are:

1. Claims 27, 28, 32-34, 36-38, 50, 69, 70, 73-76, 80, 81, 84 and 85 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Hurst *et al.* (Rapid Comm. Mass Spectrom. (1996) 10:377-382), (hereinafter “Hurst”) in view of either Muddiman *et al.* (Anal. Chem. (1997) 69:1543-1549) (hereinafter “Muddiman”) or Chen (U.S. Patent No. 6,613,509) (hereinafter “Chen”).

2. Claims 27-29, 31-35, 37, 38, 50-60, 62-71, 73-78 and 80-87 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Hoffman *et al.* (Arch. Virol. (2001) 146:2275-2289) (hereinafter “Hoffman”) in view of Koster (WO 98/20166) (hereinafter “Koster”) and further in view of Muddiman or Chen.
3. Claims 27-29, 31-35, 37, 38, 50-60, 62-71, 73-78 and 80-87 are rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1-29 of U.S. Patent No. 7,108,974, claims 1-11 of U.S. Patent No. 7,226,739, claims 1-28 of U.S. Patent No. 7,255,992, and claims 23-27, 30-34, and 44-55 of copending Application No. 10/660,122.

II. Information Disclosure Statement

Applicants will be submitting a supplemental Information Disclosure Statement (IDS) and corresponding Form 1449/PTO. This supplemental IDS includes patents, patent applications, patent publications, search reports, scientific references, and Office Communications from other patent applications owned by Applicants. Also included with the supplemental IDS is a table summarizing substantive Office Actions from Applicants’ patent application serial numbers 09/798,007, 10/156,608, 10/326,047, 10/660,997, 10/660,122, 10/660,996, 10/660,998, 10/319,290, 10/318,881, 10/319,342, 10/318,463, 10/435,307, 10/430,253, 11/233,630, 11/331,978, 11/331,987, 11/682,259, 09/891,793, 10/340,321, 10/340,482, 10/340,461, 10/340,483, 10/323,210, 10/754,415, 10/439,690, 10/439,706, 11/674,538, 11/930,108, 10/323,233, 10/728,486, 11/930,002, and 10/418,514. This table includes the dates of each Official Action, a listing of references cited under 35 U.S.C. §§ 102 or 103, a listing of other rejections or action, and a status of the applications.

Applicants also attach hereto (which will also be included in the supplemental IDS), copies of Form 1449/PTO for supplemental IDSs from each of three issued patents related to the above listed applications: 7,108,974, 7,226,739, and 7,255,992. These

supplemental IDSs were submitted in the respective applications after allowance of the respective applications and were not considered by the Examiner in those respective applications. Each of the references cited in the supplemental IDSs for the three issued patents is of record in the present application either from prior or the supplemental IDS. Applicants wish to ensure that the Examiner considers each of these references during review of the present application and does not rely on their presence in the file histories of the earlier filed, now issued, applications.

III. Rejections Under 35 U.S.C. 103(a)

Applicants initially note that claims 1-87 have been cancelled, rendering the rejections moot. Applicants note that the cancellation of claims presented herein are made without acquiescing to any of the Examiner's arguments or rejections, and are made solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG),¹ and without waiving the right to prosecute the cancelled claims (or similar claims) in the future.

Independent claims 88, 119, 147, and 178 are added, each with dependent claims. Claim 88 specifies that the method employs amplification of “two or more segments of a nucleic acid” with “two or more primer pairs to obtain two or more amplification products”, that base compositions are determined from the amplification products, and that one or more etiologic agents are identified by comparing the determined base compositions to known base compositions of known etiologic agents produced with the two or more primer pairs.

Claim 119 specifies that the method employs amplification of “two or more segments of a nucleic acid” with “two or more primer pairs to obtain two or more amplification products”, that base compositions are determined from the amplification products, and that one or more bioagents are identified by comparing the determined base compositions to known base compositions of known bioagents produced with the two or more primer pairs.

¹ 65 Fed. Reg. 54603 (Sept. 8, 2000).

Claim 147 specifies that the method employs amplification of “two or more segments of a nucleic acid” with “two or more primer pairs to obtain two or more amplification products” with primer pairs that hybridize to “conserved regions of the nucleic acid that flank a variable region”, that base compositions are determined from the amplification products, and that one or more bioagents are identified by comparing the determined base compositions with a database containing known base compositions of known bioagents produced with the two or more primer pairs.

Claim 178 specifies that the method employs amplification of “two or more segments of a nucleic acid” with “two or more primer pairs to obtain two or more amplification products” with primer pairs that hybridize to “conserved regions of the nucleic acid that flank a variable region”, that masses are determined from the amplification products via mass spectrometry without sequencing, and that one or more bioagents are identified by comparing the masses with a database containing known masses of known bioagents produced with the two or more primer pairs.

The references (Hurst/Muddiman/Chen and Hoffman/Koster/Muddiman/Chen) cited against the previous claims, alone or in combination, do not teach or suggest the presently claimed invention.

Hurst describes the use of MALDI-TOF MS for detection of amplified bacterial DNA generated from the use of primers unique to a particular bacterium or gene being studied. Because a single primer pair is designed to uniquely identify a gene or bacterium or interest, there is a one-to-one correlation between the mass spectrum obtained from an amplicon and the gene or bacterium of interest. As such, there is no basis for utilizing a plurality of amplicons for the identification of an agent of interest. Likewise, the use of primers that amplify multiple different organisms (see e.g., claims 102-105 and 112 and their counterparts) is counter to the methods of Hurst.

Muddiman describes the use of mass spectrometry to determine the length and base composition of a PCR amplified nucleic acid. Muddiman does not teach or suggest the use of a plurality of amplicons, or comparison of their base compositions to known base compositions, for the identification of an agent of interest. Muddiman further does

not teach or suggest primers that amplify multiple different organisms (see e.g., claims 102-105 and 112 and their counterparts).

Chen describes the use of mass spectrometry to compare amplicons that are identical, but for the fact that one is isotope-labeled and the other is unlabeled, for the purpose of determining the nucleotide composition of a DNA molecule. Chen does not teach or suggest the use of a plurality of amplicons, or comparison of their base compositions to known base compositions, for the identification of an agent of interest. Chen further does not teach or suggest primers that amplify multiple different organisms (see e.g., claims 102-105 and 112 and their counterparts). Indeed, the complexity of such a sample would confound the methods of Chen and be counter to the teachings of Chen, as Chen's approach is directed at a comparison of one specific molecule to itself in labeled and unlabeled forms.

Hoffman is not prior art. As noted above, the priority date of the present application is March 2, 2001, which predates the publication date of Hoffman.

Koster describes a MALDI TOF mass spectroscopy-based method for determining the sequence of DNA molecules. Koster does not teach or suggest the use of a plurality of amplicons, or comparison of their base compositions to known base compositions, for the identification of an agent of interest. Koster further does not teach or suggest primers that amplify multiple different organisms (see e.g., claims 102-105 and 112 and their counterparts).

In view of the above, Applicants believe that none of the cited references, taken alone or collectively, teach or suggest the presently claimed invention. These references do not teach or suggest methods that employ the use of a plurality of amplification products or comparison of their base compositions to known base compositions for the identification of an agent of interest. These references also do not teach or suggest use of primers that amplify nucleic acid from multiple different organisms to generate amplification products whose base compositions are compared to a database of known base compositions generated using the primers. The combination of Hurst, Muddiman, and Chen lacks these teachings. The combination of Hoffman/Koster/Muddiman/Chen is not applicable because Hoffman is not prior art. Thus, the cited art, even if combined

(Applicants asserted that there is no proper legal motivation to combine the references, nor expectation of success in their combination for the reasons of record), does not provide all of the elements of the presently claimed invention.

Further, evidence in the record provided by the previously submitted Buchsbaum Declaration evidences the non-obviousness of the presently claimed invention. The evidence provided in the Buchsbaum Declaration shows that results demonstrated in the present application were unexpected, even in view of existing technologies such as general broad range priming and mass spectrometry technologies. The Buchsbaum Declaration also evidences skepticism about the technology by an independent scientific advisory group. The Buchsbaum Declaration further identifies the impact made by the technology, including its description in prominent scientific journals.

Despite this evidence, the Office Action dismisses the Buchsbaum Declaration for the reasons of record (“A response to this Declaration was presented in the previous Final Office Action of May 11, 2007 and will not be repeated here”; page 17). The Final Office Action to which the present Office Action references dismissed the declaration because the claims pending at that time did not, according to the Examiner, have sufficient nexus to the skepticism described in the Declaration. In particular, the claims pending at time did not recite the use of primers to generate multiple different amplification products that could be used to identify a bioagent or bioagents by comparing base compositions to known bioagent base compositions. Accordingly, each of the present claims recites inventions that correspond to the evidence conveyed in the Declaration. Independent claims 88 and 119 describe methods wherein at least two or more sets of primers are used to generate two or more amplification products, which in turn are used to identify an agent by comparison to base compositions of known agents generated using the primers. Independent claims 147 and 178 recite the use of broad range priming to generate multiple amplification products and performance of a comparison with a database of targets to identify a bioagent.

An embodiment of these claims (both independent and dependent claims) is the triangulation approach described in the specification at pages 20-21, and exemplified in Figure 17. These embodiments highlight the power of the technology described in the

application, providing techniques to identify and differentiate known and unknown organisms and resolve extremely complex information using a small number of primer pairs and the information conveyed in base composition data. By combining information obtained from a plurality of amplification products generated by multiple primer pairs, extraordinary discrimination capability can be achieved, including the ability to identify one or more unknown bioagents at multiple levels (e.g., genus, species, sub-type, etc.). The publications attached to the Buchsbaum Declaration describe such results. Clearly, nothing in the cited references teaches or suggests these approaches, or demonstrates that information conveyed by base composition data provides the discrimination and identification power obtained with such embodiments of the invention. Only through the inventive work of the present inventors was such a technology realized or realizable.

For the reasons described above, Applicants believe that prima facie obviousness cannot be properly established against the present claims, and request that the claims be passed to allowance.

IV. DOUBLE PATENTING

Upon indication of otherwise allowable subject matter, Applicants will consider the filing of a Terminal Disclaimer to obviate the double patenting rejections.

CONCLUSION

All grounds of rejection of the Office Action have been addressed, and reconsideration of the application is respectfully requested. It is respectfully submitted that Applicants' claims as amended should be passed into allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourage the Examiner to call the undersigned collect at (608) 218-6900.

Dated: April 17, 2008

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UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,996	09/12/2003	David J. Ecker	DIBIS-0002US.P4	7769
58057 7590 07/10/2007 MEDLEN & CARROLL LLP 101 HOWARD STREET SUITE 350 SAN FRANCISCO, CA 94105			EXAMINER FREDMAN, JEFFREY NORMAN	
			ART UNIT 1637	PAPER NUMBER
			MAIL DATE 07/10/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
10660996			
			EXAMINER
			ART UNIT PAPER

DATE MAILED:

NOTICE OF NON-COMPLIANT INFORMATION DISCLOSURE STATEMENT

An Information Disclosure Statement (IDS) filed 2-21-07 in the above-identified application fails to meet the requirements of 37 CFR 1.97(d) for the reason(s) specified below. Accordingly, the IDS will be placed in the file, but the information referred to therein has not been considered.

The IDS is not compliant with 37 CFR 1.97(d) because:

- ☒ The IDS lacks a statement as specified in 37 CFR 1.97(e).
- ☐ The IDS lacks the fee set forth in 37 CFR 1.17(p).
- ☐ The IDS was filed after the issue fee was paid. Applicant may wish to consider filing a petition to withdraw the application from issue under 37 CFR 1.313(c) to have the IDS considered. See MPEP 1308.

WJ
initials

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NUMBER: **10/660,996**
FILING DATE: **09/12/2003**
FIRST NAMED INVENTOR: **David J. Ecker**
ART UNIT: **1637**
EXAMINER NAME: **Jeffrey Norman Fredman**
ATTORNEY DOCKET NUMBER: **DIBIS-0002US.P4 (10448)**
TITLE: **METHOD FOR RAPID DETECTION AND
IDENTIFICATION OF BIOAGENTS FOR
ENVIRONMENTAL AND PRODUCT
TESTING**

MAIL STOP AMENDMENT
COMMISSIONER FOR PATENTS
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
Under 37 C.F.R. §§ 1.56 and 1.97-98

SIR:

Pursuant to the provisions of 37 C.F. R. §§ 1.56 and 1.97-98, enclosed herewith is PTO Forms PTO/SB/08A and PTO/SB/08B listing references for consideration by the Examiner.

Documents disclosed herein are those compiled from United States Patent Applications related to the instant application. Examiner has already considered many of these documents in the related cases in which they were filed.

The filing of this Information Disclosure Statement shall not be construed as a representation regarding the completeness of the list of references, or that inclusion of a reference in this list is an admission that it is prior art or is pertinent to this application, or that a search has been made, or as an admission that the information listed is, or may be

considered to be, material to patentability, or that no other material information exists, and shall not be construed as an admission against interest in any manner.

This Information Disclosure Statement is being filed:

- ☐ within three months of the filing date of the application, or date of entry into the national stage of an international application, or before the mailing date of a first office action on the merits, whichever event last occurred;
- ☐ before the mailing of a first official action after filing of a request for continued examination (RCE) under 37 C.F.R. § 1.114;
- ☐ after three months of the filing date of this national application or the date of entry of the national stage in an international application, or after the mailing date of the first official action on the merits, whichever event last occurred, but before that mailing date of the first office action to occur of either: (1) a final action under 37 C.F.R. § 1.113; or (2) an action that otherwise closes prosecution in the application, and:

- ☐ attached hereto is the fee set forth under 37 C.F.R. § 1.17(p) for submission of this Information Disclosure Statement under 37 C.F.R. § 1.97(c); OR

- ☐ Applicant certifies pursuant to 37 C.F.R. § 1.97(e) that:

- ☐ each item of the information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement;

OR

- ☐ no item of information contained in this Information Disclosure Statement was cited in a counterpart foreign application and, to the knowledge of the person signing this certification after making reasonable inquiry, no item of information contained in this Statement was known to any individual designated under 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Statement.

☒ on or before the payment of the issue fee but after the mailing date of the first to occur of either: (1) a final action under 37 C.F.R. § 1.113; (2) a notice of allowance under 37 C.F.R. § 1.311; or (3) an action that otherwise closes prosecution in the application, and:

☐ Applicant certifies pursuant to 37 C.F.R. § 1.97(e) that:

☐ each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement;

OR

☐ no item of information contained in this Information Disclosure Statement was cited in a counterpart foreign application and, to the knowledge of the person signing this certification after making reasonable inquiry, no item of information contained in this Statement was known to any individual designated under 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Statement. AND

☒ attached hereto is the fee set forth under 37 C.F.R. § 1.17(p) for submission of this Information Disclosure Statement under 37 C.F.R. § 1.97(c); OR

☐ after the payment of the issue fee. Applicant requests that the information contained in this Information Disclosure Statement be placed in the file according to 37 C.F.R. § 1.97(i), although the information may not be considered by the USPTO.

☒ Enclosed is a copy of each listed reference that may be material to the examination of this application, and for which there may be a duty to disclose.

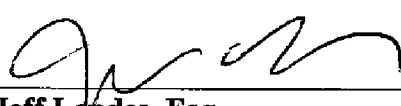
☐ This application relies, under 35 U.S.C. § 120, on the earlier filing date of prior application No. _____, filed on _____, and the references cited therein are hereby referenced, but are not required to be provided in this application under 37 C.F.R. § 1.98(d).

☒ This application was filed after June 30, 2003. Therefore, pursuant to the waiver of the requirements under 37 C.F.R. § 1.98(a)(2)(i), copies of each U.S. Patent and each U.S. Patent Application Publication are not required to be submitted. Copies of any foreign patent documents and non-patent literature cited herein are enclosed.

☐ Each item of information contained in this Information Disclosure Statement was cited in the communication from a foreign patent office in a counterpart application, and the communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of this Information Disclosure Statement 37 C.F.R. § 1.704(d).

☐ Applicant submits that no fee is required for the consideration of this Information Disclosure Statement. However, if a fee is due, the Commissioner is hereby authorized to charge Deposit Account No 500252 referencing case number .
Consideration of the listed references and favorable action are solicited.

Respectfully submitted,



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Carlsbad, CA 92008

Dated: 2/20/2007

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

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of

12

Complete if Known

Application Number	10/660,996
Filing Date	09/12/2003
First Named Inventor	David J. Ecker
Art Unit	1637
Examiner Name	Jeffrey Norman Fredman
Attorney Docket Number	DIBIS-0002US.P4

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
	CP	US-5,484,908	01-16-1996	Fröhler et al.	
	CQ	US-5,502,177	03-26-1996	Matteucci et al.	
	CR	US-5,503,980	04-02-1996	Cantor	
	CS	US-5,527,675	06-18-1996	Coull et al.	
	CT	US-5,580,733	12-03-1996	Levis et al.	
	CU	US-5,625,184	04-29-1997	Vestal et al.	
	CV	US-5,645,985	07-08-1997	Fröhler et al.	
	CW	US-5,686,242	11-11-1997	Bruice et al.	
	CX	US-5,700,642	12-23-1997	Monforte et al.	
	CY	US-5,759,771	06-02-1998	Tilanus	
	CZ	US-5,763,588	07-09-1998	Matteucci et al.	
	DA	US-5,770,367	06-23-1998	Southern et al.	
	DB	US-5,777,324	07-07-1998	Hillenkamp	
	DC	US-5,830,653	11-03-1998	Fröhler et al.	
	DD	US-5,830,655	11-03-1998	Monforte et al.	
	DE	US-5,851,765	12-22-1998	Koster	
	DF	US-5,864,137	01-26-1999	Becker et al.	
	DG	US-5,869,242	02-09-1999	Kamb	
	DH	US-5,871,697	02-16-1999	Rothberg et al.	
	DI	US-5,876,936	03-02-1999	Ju	
	DJ	US-5,928,906	07-27-1999	Koster et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁸
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
	DK	DE19802905	07-29-1999	Bruker Daltonik		
	DL	DE19824280	12-02-1999	Bruker Daltonik		
	DM	DE19852167	05-31-2000	Bruker Saxonia		
	DN	EP1138782	10-14-2001	Bruker Saxonia		
	DO	EP1234888	08-28-2002	Bruker Saxonia		
	DP	EP1333101	08-06-2003	Bruker Daltonik		
	DQ	GB2325002	11-11-1998	Bruker Franzen		
	DR	GB2339905	02-09-2000	Bruker Daltonik		
	DS	WO 93/03186	02-18-1993	Hoffman-La Roche		
	DT	WO 94/16101	07-21-1994	Koster		

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 2 of 12

Complete if Known

Application Number	10/660,996
Filing Date	09/12/2003
First Named Inventor	David J. Ecker
Art Unit	1637
Examiner Name	Jeffrey Norman Fredman
Attorney Docket Number	DIBIS-0002US.P4

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		Number - Kind Code ² (if known)			
	DU	US-5,981,176	11-09-1999	Wallace	
	DV	US-5,994,066	11-30-1999	Bergeron et al.	
	DW	US-6,001,564	12-14-1999	Bergeron et al.	
	DX	US-6,005,096	12-21-1999	Matteucci et al.	
	DY	US-6,007,992	12-28-1999	Lin et al.	
	DZ	US-6,028,183	02-22-2000	Lin et al.	
	EA	US-6,046,005	04-04-2000	Ju et al.	
	EB	US-6,051,378	04-18-2000	Monforte et al.	
	EC	US-6,054,278	04-25-2000	Dodge et al.	
	ED	US-6,074,823	06-13-2000	Koster	
	EE	US-6,090,558	07-18-2000	Butler et al.	
	EF	US-6,104,028	08-15-2000	Hunter et al.	
	EG	US-6,111,251	08-29-2000	Hillenkamp	
	EH	US-6,140,053	10-31-2000	Koster	
	EI	US-6,146,144	11-14-2000	Fowler et al.	
	EJ	US-6,153,389	11-28-2000	Haarer et al.	
	EK	US-6,159,681	12-12-2000	Zebala	
	EL	US-6,180,372	01-30-2001	Franzen	
	EM	US-6,194,144	02-27-2001	Koster	
	EN	US-6,197,498	03-06-2001	Koster	

FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ³
		Country Code ⁵ - Number ⁴ - Kind Code ⁶ (if known)				
	EO	WO 94/21822	09-24-1994	Koster		
	EP	WO 96/29431	09-26-1996	Sequenom		
	EQ	WO 96/32504	10-17-1996	Trust. of Boston		
	ER	WO 96/37630	11-28-1996	SRI International		
	ES	WO 98/03684	01-29-1998	Hybridon Inc.		
	ET	WO 98/14616	04-09-1998	Perceptive Bio.		
	EU	WO 98/15652	04-16-1998	Brax Genomics		
	EV	WO 98/20020	05-14-1998	Sequenom Inc.		
	EW	WO 98/20157	05-14-1998	Infectio Diagnost.		
	EX	WO 98/26095	06-18-1998	Genetrace Sys.		

Examiner
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Complete if Known

Application Number	10/660,996
Filing Date	09/12/2003
First Named Inventor	David J. Ecker
Art Unit	1637
Examiner Name	Jeffrey Norman Fredman
Attorney Docket Number	DIBIS-0002US.P4

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
	EY	US-6,218,118	04-17-2001	Sampson et al.	
	EZ	US-6,221,601	04-24-2001	Koster et al.	
	FA	US-6,221,605	04-24-2001	Koster	
	FB	US-6,225,450	05-01-2001	Koster	
	FC	US-6,235,476	05-22-2001	Bergmann et al.	
	FD	US-6,235,478	05-22-2001	Koster	
	FE	US-6,235,480	05-22-2001	Shultz et al.	
	FF	US-6,238,871	05-29-2001	Koster	
	FG	US-6,238,927	05-29-2001	Abrams et al.	
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	FI	US-6,265,716	07-24-2001	Hunter et al.	
	FJ	US-6,268,129	07-31-2001	Gut et al.	
	FK	US-6,268,131	07-31-2001	Kang et al.	
	FL	US-6,268,144	07-31-2001	Koster	
	FM	US-6,268,146	07-31-2001	Shultz et al.	
	FN	US-6,270,973	08-07-2001	Lewis et al.	
	FO	US-6,270,974	08-07-2001	Shultz et al.	
	FP	US-6,277,573	08-21-2001	Koster	
	FQ	US-6,277,578	08-21-2001	Shultz et al.	
	FR	US-6,300,076	10-09-2001	Koster	

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		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
	FS	WO 98/31830	07-23-1998	Brax Genomics		
	FT	WO 98/40520	09-17-1998	Hybridon Inc.		
	FU	WO 99/05319	02-04-1999	Rapigene, Inc.		
	FV	WO 99/29898	06-17-1999	Max-Planck		
	FW	WO 99/57318	11-11-1999	Sequenom Inc.		
	FX	WO 01/07648	02-01-2001	Artus Gesell.		
*	FY	WO 01/23604	04-05-2001	Infectio Diagnost.		
	FZ	WO 01/32930	05-10-2001	California Instit.		
	GA	WO 01/51661	07-19-2001	Amsterdam Support		
	GB	WO 01/57263	08-09-2001	Advion Biosci.		

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Art Unit	1637
Examiner Name	Jeffrey Norman Fredman
Attorney Docket Number	DIBIS-0002US.P4

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		Number - Kind Code ² (if known)			
	GC	US-6,312,893	11-06-2001	Van Ness et al.	
	GD	US-6,312,902	11-06-2001	Shultz et al.	
	GE	US-6,361,940	03-26-2002	Van Ness et al.	
	GF	US-6,372,424	04-16-2002	Brow et al.	
	GG	US-6,391,551	05-21-2002	Shultz et al.	
	GH	US-6,423,966	07-23-2002	Hillenkamp et al.	
	GI	US-6,428,955	08-06-2002	Koster et al.	
	GJ	US-6,432,651	08-13-2002	Hughes et al.	
	GK	US-6,436,635	08-20-2002	Fu et al.	
	GL	US-6,436,640	08-20-2002	Simmons et al.	
	GM	US-6,458,533	10-01-2002	Felder et al.	
	GN	US-6,468,748	10-22-2002	Monforte et al.	
	GO	US-6,475,736	11-05-2002	Stanton, Jr.	
	GP	US-6,479,239	11-12-2002	Anderson et al.	
	GQ	US-6,500,621	12-31-2002	Koster	
	GR	US-6,558,902	05-06-2003	Hillenkamp	
	GS	US-6,566,055	05-20-2003	Monforte et al.	
	GT	US-6,582,916	06-24-2003	Schmidt et al.	
	GU	US-6,589,485	07-08-2003	Koster	

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	GV	WO 02/10186	02-07-2002	California Instit.		
	GW	WO 02/18641	03-07-2002	Sequenom-Gemini		
	GX	WO 02/21108	03-14-2002	Large Scale		
	GY	WO 02/50307	06-27-2002	Chugai Selyaku		
	GZ	WO 02/57491	07-25-2002	Board of Trustees of the Leland		
	HA	WO 02/077278	10-03-2002	Council of Scientific		
	HB	WO 02/099034	12-12-2002	Infection Diagnostic		
	HC	WO 03/002750	01-09-2003	High Throughput		
	HD	WO 03/008636	01-30-2003	Infectio Diagnost.		
	HE	WO 03/016546	02-27-2003	Flinders Technol.		

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Sheet 5 of 12

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Application Number	10/660,996
Filing Date	09/12/2003
First Named Inventor	David J. Ecker
Art Unit	1637
Examiner Name	Jeffrey Norman Fredman
Attorney Docket Number	DIBIS-0002US.P4

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		Number - Kind Code ² (if known)			
	HF	US-6,602,662	08-05-2003	Koster	
	HG	US-6,605,433	08-12-2003	Fliss et al.	
	HH	US-6,623,928	09-23-2003	Van Ness et al.	
	HI	US-6,682,889	08-12-2003	Fliss et al.	
	HJ	US-6,716,634	04-06-2004	Myerson	
	HK	US-2002/0045178	04-18-2002	Cantor et al.	
	HL	US-2002/0137057	09-26-2002	Wold et al.	
	HM	US-2002/0150903	10-17-2002	Koster	
	HN	US-2002/0150927	10-17-2002	Matray et al.	
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	HQ	US-2003/0039976	02-27-2003	Haff	
	HR	US-2003/0064483	04-03-2003	Shaw et al.	
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	HU	US-2003/0129589	07-10-2003	Koster et al.	
	HV	US-2003/0134312	07-17-2003	Burgoyne	
	HW	US-2003/0148284	08-07-2003	Vision et al.	
	HX	US-2003/0175729	09-18-2003	Van Eijk et al.	
	HY	US-2003/0194699	10-16-2003	Lewis et al.	
	HZ	US-2003/0203398	10-30-2003	Bramucci et al.	
	IA	US-2003/0220844	11-27-2003	Marnellos et al.	
	IB	US-2004/0005555	01-08-2004	Rothman et al.	
	IC	US-2004/0038206	02-26-2004	Zhang et al.	
	ID	US-2004/0038234	02-26-2004	Gut et al.	
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		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
	IF	WO 03/060163	07-24-2003	Keygene N.V.		
	IG	WO 03/088979	10-30-2003	Centre National		
	IH	WO 03/097869	11-27-2003	Con/Cipio GmbH		

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Sheet 6 of 12

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Application Number	10/660,996
Filing Date	09/12/2003
First Named Inventor	David J. Ecker
Art Unit	1637
Examiner Name	Jeffrey Norman Fredman
Attorney Docket Number	DIBIS-0002US.P4

NON PATENT LITERATURE DOCUMENTS

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	II	BAHRMAND, A. R. et al., "Use of restriction enzyme analysis of amplified DNA coding for the hsp65 gene and polymerase chain reaction with universal primer for rapid differentiation of mycobacterium species in the clinical laboratory," <i>Scand. J. Infect. Diseases</i> (1998) 30(5):477-80.	
	IJ	BAHRMAND, A. R. et al., "Polymerase chain reaction of bacterial genomes with single universal primer: application to distinguishing mycobacteria species," <i>Mol. Cell. Probes</i> (1996) 10(2):117-122.	
	IK	BASTIA, T. et al., "Organelle DNA analysis of Solanum and Brassica somatic hybrids by PCR with 'universal primers'," <i>Theoretical and Applied Genetics</i> (2001) 102(8):1265-1272.	
	IL	BOIVIN-JAHNS, V. et al., "Bacterial Diversity in a Deep-Subsurface Clay Environment," <i>Appl. Environ. Microbiol.</i> (1996) 62(9):3405-3412.	
	IM	BOWEN, J. E. et al., "The native virulence plasmid combination affects the segregational stability of a theta-replicating shuttle vector in <i>Bacillus anthracis</i> var. New Hampshire," <i>J Appl Microbiol.</i> (1999) 87(2):270-278.	
	IN	CESPEDES, A. et al., "Polymerase chain reaction restriction fragment length polymorphism analysis of a short fragment of the cytochrome b gene for identification of flatfish species," <i>J. Food Protection</i> (1998) 61(12):1684-1685.	
	IO	CHEN, C. A. et al., "Universal primers for amplification of mitochondrial small subunit ribosomal RNA-encoding gene in scleractinian corals," <i>Marine Biotech.</i> (2000) 2(2):146-153.	
	IP	CHO, M. et al., "Application of the ribonuclease P (RNase P) RNA gene sequence for phylogenetic analysis of the gene <i>Saccharomonospora</i> ," <i>Internat. J. of Sys. Bacteriol.</i> (1998) 48:1223-1230.	
	IQ	CORNEL, A. J. et al., "Polymerase chain reaction species diagnostic assay for <i>Anopheles quadrimaculatus</i> cryptic species (Diptera: Culicidae) based on ribosomal DNA ITS2 sequences," <i>Journal of Medical Entomology</i> (1996) 33(1):109-116.	
	IR	CRAIN, P. F. et al., "Applications of mass spectrometry to the characterization of oligonucleotides and nucleic acids," <i>Curr Opin Biotechnol</i> (1998) 9(1):25-34.	
	IS	CRESPILLO, M. et al., "Mitochondrial DNA sequences for 118 individuals from northeastern Spain," <i>Int. J. Legal Med.</i> (2000) 114:130-132.	
	IT	DEFORCE, D. L. et al., "Analysis of oligonucleotides by ESI-MS," <i>Advances in Chromatography</i> (2000) 40:539-566.	

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	IU	DIAS NETO, E. et al., "Shotgun sequencing of the human transcriptome with ORF expressed sequence tags," <i>PNAS</i> (2000) 97(7):3491-3496.	
	IV	DINAUER, D. M. et al., "Sequence-based typing of HLA class II DQB1," <i>Tissue Antigens</i> (2000) 55(4):364-368.	
	IW	DUBERNET, S. et al., "A PCR-based method for identification of Lactobacilli at the genus level," <i>FEMS Microbiology Letters</i> (2002) 214(2):271-275.	
	IX	FIGUEIREDO, L. T. M. et al., "Identification of Brazilian flaviviruses by a simplified reverse transcription-polymerase chain reaction method using Flavivirus universal primers," <i>American Journal of Tropical Medicine and Hygiene</i> (1998) 59(3):357-362.	
	IY	FOX, A. et al., "Identification and detection of bacteria: electrospray MS-MS versus derivatization/GC-MS," <i>Proceedings of the ERDEC Scientific Conference on Chemical and Biological Defense Research</i> (1994) Aberdeen Proving Ground, Md., Nov. 15-18, p. 39-44.	
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	JA	GATTERMANN, N. et al., "Heteroplasmic Point Mutations of Mitochondrial DNA Affecting Subunit I of Cytochrome c Oxidase in Two Patients with Acquired Idiopathic Sideroblastic Anemia," <i>Blood</i> (1997) 90(12):4961-4972.	
	JB	GRIFFIN, T. J. et al., "Single-nucleotide polymorphism analysis by MALDI-TOF mass spectrometry," <i>Trends in Biotechnology</i> (2000) 18(2):77-84.	
	JC	HAHNER, S. et al., "Analysis of short tandem repeat polymorphisms by electrospray ion trap mass spectrometry," <i>Nucleic Acids Res.</i> (2000) 28(18):E82.	
	JD	HANNIS, J. C. et al., "Genotyping complex short tandem repeats using electrospray ionization Fourier transform ion cyclotron resonance multistage mass spectrometry," <i>Proceedings of SPIE-The International Society for Optical Engineering</i> (2000) 3926:36-47.	
	JE	HENCHAL, E. A. et al., "Sensitivity and specificity of a universal primer set for the rapid diagnosis of dengue virus infections by polymerase chain reaction and nucleic acid hybridization," <i>American Journal of Tropical Medicine and Hygiene</i> (1991) 45(4):418-428.	
	JF	HERRMANN, B. et al., "Differentiation of <i>Chlamydia</i> spp. by Sequence Determination and Restriction Endonuclease Cleavage of RNase P RNA Genes," <i>J. Clin. Microbiol.</i> (1996) 34(8): 1897-1902.	

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	JG	HIGGINS, G. S. et al., "Competitive oligonucleotide single-base extension combined with mass spectrometric detection for mutation screening," <i>BioTechniques</i> (1997) 23(4):710-714.	
	JH	HONDA, K. et al., "Universal method of hypersensitive nested PCR toward forensic DNA typing," <i>International Congress Series</i> (1998) 7:28-30.	
	JI	HURST, G. B. et al., "MALDI-TOF analysis of polymerase chain reaction products from methanotrophic bacteria," <i>Anal. Chem.</i> (1998) 70(13):2693-2698.	
	JJ	JOHNSON, Y. A. et al., "Precise molecular weight determination of CPR products of the rRNA intergenic spacer region using electrospray quadrupole mass spectrometry for differentiation of <i>B. subtilis</i> and <i>B. atrophaeus</i> , closely related species of bacilli," <i>J. Microbiol. Methods</i> (2000) 40(3):241-254.	
	JK	JURINKE, C. et al., "Detection of hepatitis B virus DNA in serum samples via nested PCR and MALDI-TOF mass spectrometry," <i>Genetic Analysis: Biomolecular Engineering</i> (1996) 13:67-71.	
	JL	KILPATRICK, D. R. et al., "Group-Specific Identification of Polioviruses by PCR Using Primers Containing Mixed-Base or Deoxyinosine Residues at Positions of Codon Degeneracy," <i>J. Clin. Microbiol.</i> (1996) 34(12):2990-2996.	
	JM	KRAHMER, M. T. et al., "Electrospray quadrupole mass spectrometry analysis of model oligonucleotides and polymerase chain reaction products: determination of base substitutions, nucleotide additions/deletions, and chemical modifications," <i>Anal. Chem.</i> (1999) 71(14):2893-2900.	
	JN	KRAHMER, M. T. et al., "MS for identification of single nucleotide polymorphisms and MS/MS for discrimination of isomeric PCR products," <i>Anal. Chem.</i> (2000) 72(17):4033-4040.	
	JO	LACROIX, J.-M. et al., "PCR-based technique for the detection of bacteria in semen and urine," <i>J. Microbiol. Methods</i> (1996) 26:61-71.	
	JP	LEIF, H. et al., "Isolation and characterization of the proton-translocating NADH: ubiquinone oxidoreductase from <i>Escherichia coli</i> ," <i>Eur. J. Biochem.</i> (1995) 230(2):538-548.	
	JQ	LI, J. et al., "Single nucleotide polymorphism determination using primer extension and time-of-flight mass spectrometry," <i>Electrophoresis</i> (1999) 20(6):1258-1265.	
	JR	LIU, Y. et al., "An unusual gene arrangement for the putative chromosome replication origin and circadian expression of <i>dnaN</i> in <i>Synechococcus</i> sp. strain PCC 7942," <i>Gene</i> (1996) 172(1):105-109.	

Examiner
SignatureDate
Considered

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet

9

of

12

Complete if Known

Application Number	10/660,996
Filing Date	09/12/2003
First Named Inventor	David J. Ecker
Art Unit	1637
Examiner Name	Jeffrey Norman Fredman
Attorney Docket Number	DIBIS-0002US.P4

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	JS	LOAKES, D. et al., "Nitroindoles as Universal Bases," <i>Nucleosides Nucleotides</i> (1995) 14:1001-1003.	
	JT	LOVE, B. C. et al., "Cloning and sequence of the <i>groESL</i> heat-shock operon of <i>Pasteurella multocida</i> ," <i>Gene</i> (1995) 166(1):179-180.	
	JU	MAIWALD, M. et al., "Characterization of contaminating DNA in Taq polymerase which occurs during amplification with a primer set for <i>Legionella</i> 5S ribosomal RNA," <i>Mol. Cell. Probes</i> (1994) 8(1):11-14.	
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	JW	MATRAY, T. J. et al., "Synthesis and properties of RNA analogs - oligoribonucleotide N3'→P5' phosphoramidates," <i>Nucleic Acids Res.</i> (1999) 27(20):3976-3985.	
	JX	MESSMER, T. O. et al., "Discrimination of <i>Streptococcus pneumoniae</i> from other upper respiratory tract streptococci by arbitrarily primed PCR," <i>Clin. Biochem.</i> (1995) 28(6):567-572.	
	JY	MORSE, R. et al., "Nucleotide Sequence of Part of the <i>ropC</i> Gene Encoding the β ' Subunit of DNA-Dependent RNA Polymerase from some Gram-Positive Bacteria and Comparative Amino Acid Sequence Analysis," <i>System Appl. Microbiol.</i> (1996) 19:150-157.	
	JZ	MUDDIMAN, D. C. et al., "Application of secondary ion and matrix-assisted laser desorption-ionization time-of-flight mass spectrometry for the quantitative analysis of biological molecules," <i>Mass Spectrometry Reviews</i> (1996) 14(6):383-429.	
	KA	MUDDIMAN, D. C. et al., "Important aspects concerning the quantification of biomolecules by time-of-flight secondary-ion mass spectrometry," <i>Applied Spectroscopy</i> (1996) 50(2):161-166.	
	KB	MUHAMMAD, W. T. et al., "Electrospray ionization quadrupole time-of-flight mass spectrometry and quadrupole mass spectrometry for genotyping single nucleotide substitutions in intact polymerase chain reaction products in K-ras and p53," <i>Rapid Commun. Mass Spectrom.</i> (2002) 16(24):2278-2285.	
	KC	MUSHEGIAN, A. R. et al., "A minimal gene set for cellular life derived by comparison of complete bacterial genomes," <i>Proc. Natl. Acad. Sci. USA</i> (1996) 93(19):10268-10273.	
	KD	NAKAO, H. et al., "Development of a Direct PCR Assay for Detection of the Diphtheria Toxin Gene," <i>J. Clin. Microbiol.</i> (1997) 35(7):1651-1655.	

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Sheet 10 of 12

Complete If Known

Application Number	10/660,996
Filing Date	09/12/2003
First Named Inventor	David J. Ecker
Art Unit	1637
Examiner Name	Jeffrey Norman Fredman
Attorney Docket Number	DIBIS-0002US.P4

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	KE	NAUMOV, G. I. et al., "Discrimination between the soil yeast species <i>Williopsis saturnus</i> and <i>Williopsis suaveolens</i> by the polymerase chain reaction with the universal primer N21," <i>Microbiology</i> (Moscow)(Translation of <i>Mikrobiologiya</i>) (2000) 69(2):229-233.	
	KF	NISHIKAWA, T. et al., "Reconstitution of active recombinant Shiga toxin (Stx)1 from recombinant Stx1-A and Stx1-B subunits independently produced by <i>E. coli</i> clones," <i>FEMS Microbiol. Lett.</i> (1999) 178:13-18.	
	KG	REID, S. M. et al., "Primary diagnosis of foot-and-mouth disease by reverse transcription polymerase chain reaction," <i>Journal of Virological Methods</i> (2000) 89(1-2):167-176.	
	KH	REILLY, K. et al., "Design and use of 16S ribosomal DNA-directed primers in competitive PCRs to enumerate proteolytic bacteria in the rumen," <i>Microbiol. Ecol.</i> (2002) 43(2):259-270.	
	KI	ROSS, P. L. et al., "Analysis of DNA fragments from conventional and microfabricated PCR devices using delayed extraction MALDI-TOF mass spectrometry," <i>Anal. Chem.</i> (1998) 70(10):2067-2073.	
	KJ	SALA, M. et al., "Ambiguous base pairing of the purine analogue 1-(2-deoxy- β -D-ribofuranosyl)-imidazole-4-carboxamide during PCR," <i>Nucleic Acids Res.</i> (1996) 24(17):3302-6.	
	KK	SAUER, S. et al., "A novel procedure for efficient genotyping of single nucleotide polymorphisms," <i>Nucleic Acids Res.</i> (2000) 28(5):E13.	
	KL	SCHRAM, K. H., "Mass Spectrometry of Nucleic Acid Components," <i>Biomedical Applications of Mass Spectrometry</i> (1990) 34:203-280.	
	KM	SCHULTZ, J. C. et al., "Polymerase chain reaction products analyzed by charge detection mass spectrometry," <i>Rapid Communications in Mass Spectrometry</i> (1999) 13(1):15-20.	
	KN	SESHADRI, R. et al., "Differential Expression of Translational Elements by Life Cycle Variants of <i>Coxiella burnetii</i> ," <i>Infect. Immun.</i> (1999) 67(11):6026-6033.	
	KO	SHAVER, Y. J. et al., "Variation in 16S-23S rRNA intergenic spacer regions among <i>Bacillus subtilis</i> 168 isolates," <i>Molecular Microbiology</i> (2001) 42(1):101-109.	
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	KQ	TONG, J. et al., "Ligation reaction specificities of an NAD ⁺ -dependent DNA ligase from the hyperthermophile <i>Aquifex aeolicus</i> ," <i>Nucleic Acids Res.</i> (2000) 28(6):1447-1454.	

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet

11

of

12

Complete If Known

Application Number	10/660,996
Filing Date	09/12/2003
First Named Inventor	David J. Ecker
Art Unit	1637
Examiner Name	Jeffrey Norman Fredman
Attorney Docket Number	DIBIS-0002US.P4

NON PATENT LITERATURE DOCUMENTS

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	KR	VAN AERSCHOT, A. et al., "In search of acyclic analogues as universal nucleosides in degenerate probes," <i>Nucleosides & Nucleotides</i> (1995) 14(3-5):1053-1056.	
	KS	VAN BAAR, B. L., "Characterisation of bacteria by matrix-assisted laser desorption/ionisation and electrospray mass spectrometry," <i>FEMS Microbiol. Rev.</i> (2000) 24(2):193-219.	
	KT	VAN CAMP, G. et al., "Amplification and sequencing of variable regions in bacterial 23S ribosomal RNA genes with conserved primer sequences," <i>Curr. Microbiol.</i> (1993) 27(3):147-151.	
	KU	VAN ERT, M. N. et al., "Mass spectrometry provides accurate characterization of two genetic marker types in <i>Bacillus anthracis</i> ," <i>Biotechniques</i> (2004) 37(4):642-651.	
	KV	WALTERS, J. J. et al., "Genotyping single nucleotide polymorphisms using intact polymerase chain reaction products by electrospray quadrupole mass spectrometry," <i>Rapid Commun. Mass Spectrom.</i> (2001) 15(18):1752-1759.	
	KW	WELHAM, K. J. et al., "The Characterization of Micro-organisms by Matrix-assisted Laser Desorption/Ionization Time-of-flight Mass Spectrometry," <i>Rapid Commun. Mass Spec.</i> (1988) 12:176-180.	
	KX	WIDJOJOATMODJO, M. N. et al., "Rapid identification of bacteria by PCR-single-strand conformation polymorphism," <i>J. Clin. Microbiol.</i> (1994) 32(12):3002-3007.	
	KY	WOLTER, A. et al., "Negative Ion FAB Mass Spectrometric Analysis of Non-Charged Key Intermediates in Oligonucleotide Synthesis: Rapid Identification of Partially Protected Dinucleoside Monophosphates," <i>Biomed. Environ. Mass Spectrom.</i> (1987) 14:111-116.	
	KZ	WOO, T. H. S. et al., "Identification of <i>Leptospira inadai</i> by continuous monitoring of fluorescence during rapid cycle PCR," <i>Systematic and Applied Microbiology</i> (1998) 21(1):89-96.	
	LA	WUNSCHER, D. et al., "Discrimination among the <i>B. cereus</i> group, in comparison to <i>B. subtilis</i> , by structural carbohydrate profiles and ribosomal RNA spacer region PCR," <i>Systematic and Applied Microbiology</i> (1995) 17(4):625-635.	
	LB	WUNSCHER, D. S. et al., "Analysis of double-stranded polymerase chain reaction products from the <i>Bacillus cereus</i> group by electrospray ionization Fourier transform ion cyclotron resonance mass spectrometry," <i>Rapid Communications in Mass Spectrometry</i> (1996) 10(1):29-35.	
	LC	YAO, Z.-P. et al., "Mass Spectrometry-Based Proteolytic Mapping for Rapid Virus Identification," <i>Anal. Chem.</i> (2002) 74(11):2529-2534.	

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Application Number	10/660.996
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<i>Filing Date</i>	09/12/2003
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First Named Inventor	David J. Ecker
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Art Unit	1637
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Examiner Name	Jeffrey Norman Fredman
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Sheet	12	of	12
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Attorney Docket Number	DIBIS-0002US.P4
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Examiner Signature		Date Considered	
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,997	09/12/2003	David J. Ecker	DIBIS-0002US.P2	7707
58057 7590 04/26/2007 MEDLEN & CARROLL LLP 101 HOWARD STREET SUITE 350 SAN FRANCISCO, CA 94105			EXAMINER FREDMAN, JEFFREY NORMAN	
			ART UNIT 1637	PAPER NUMBER
			MAIL DATE 04/26/2007	DELIVERY MODE PAPER

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
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EXAMINER

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Commissioner for Patents

The information disclosure statement filed February 20, 2007 fails to comply with 37 CFR 1.97(d) because it lacks a statement as specified in 37 CFR 1.97(e). It has been placed in the application file, but the information referred to therein has not been considered.

In particular, given the large number of references (if the lettering is correct, from CQ to LF, where each letter has 26 references, then this IDS comprises 226 references) and the lack of clarity on which references were considered in related cases and which references are newly submitted for the first time, the IDS is not considered.


Jeffrey Fredman
Primary Examiner
Art Unit 1637
4/24/07

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NUMBER: **10/660,997**
FILING DATE: **09/12/2003**
FIRST NAMED INVENTOR: **David J. Ecker**
ART UNIT: **1637**
EXAMINER NAME: **Jeffrey Norman Fredman**
ATTORNEY DOCKET NUMBER: **DIBIS-0002US.P2 (10467)**
TITLE: **METHOD FOR RAPID DETECTION AND
IDENTIFICATION OF BIOAGENTS IN
EPIDEMIOLOGICAL AND FORENSIC
INVESTIGATIONS**

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
Under 37 C.F.R. §§ 1.56 and 1.97-98

SIR:

Pursuant to the provisions of 37 C.F. R. §§ 1.56 and 1.97-98, enclosed herewith is PTO Forms PTO/SB/08A and PTO/SB/08B listing references for consideration by the Examiner.

Documents disclosed herein are those compiled from United States Patent Applications related to the instant application. Examiner has already considered many of these documents in the related cases in which they were filed.

The filing of this Information Disclosure Statement shall not be construed as a representation regarding the completeness of the list of references, or that inclusion of a reference in this list is an admission that it is prior art or is pertinent to this application, or that a search has been made, or as an admission that the information listed is, or may be

considered to be, material to patentability, or that no other material information exists, and shall not be construed as an admission against interest in any manner.

This Information Disclosure Statement is being filed:

- ☐ within three months of the filing date of the application, or date of entry into the national stage of an international application, or before the mailing date of a first office action on the merits, whichever event last occurred;
- ☐ before the mailing of a first official action after filing of a request for continued examination (RCE) under 37 C.F.R. § 1.114;
- ☐ after three months of the filing date of this national application or the date of entry of the national stage in an international application, or after the mailing date of the first official action on the merits, whichever event last occurred, but before that mailing date of the first office action to occur of either: (1) a final action under 37 C.F.R. § 1.113; or (2) an action that otherwise closes prosecution in the application, and:

- ☐ attached hereto is the fee set forth under 37 C.F.R. § 1.17(p) for submission of this Information Disclosure Statement under 37 C.F.R. § 1.97(c); OR

- ☐ Applicant certifies pursuant to 37 C.F.R. § 1.97(e) that:

- ☐ each item of the information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement;

OR

- ☐ no item of information contained in this Information Disclosure Statement was cited in a counterpart foreign application and, to the knowledge of the person signing this certification after making reasonable inquiry, no item of information contained in this Statement was known to any individual designated under 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Statement.

☒ on or before the payment of the issue fee but after the mailing date of the first to occur of either: (1) a final action under 37 C.F.R. § 1.113; (2) a notice of allowance under 37 C.F.R. § 1.311; or (3) an action that otherwise closes prosecution in the application, and:

☐ Applicant certifies pursuant to 37 C.F.R. § 1.97(e) that:

☐ each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement;

OR

☐ no item of information contained in this Information Disclosure Statement was cited in a counterpart foreign application and, to the knowledge of the person signing this certification after making reasonable inquiry, no item of information contained in this Statement was known to any individual designated under 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Statement. AND

☒ attached hereto is the fee set forth under 37 C.F.R. § 1.17(p) for submission of this Information Disclosure Statement under 37 C.F.R. § 1.97(c); OR

☐ after the payment of the issue fee. Applicant requests that the information contained in this Information Disclosure Statement be placed in the file according to 37 C.F.R. § 1.97(i), although the information may not be considered by the USPTO.

☒ Enclosed is a copy of each listed reference that may be material to the examination of this application, and for which there may be a duty to disclose.

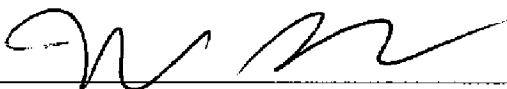
☐ This application relies, under 35 U.S.C. § 120, on the earlier filing date of prior application No. _____, filed on _____, and the references cited therein are hereby referenced, but are not required to be provided in this application under 37 C.F.R. § 1.98(d).

☒ This application was filed after June 30, 2003. Therefore, pursuant to the waiver of the requirements under 37 C.F.R. § 1.98(a)(2)(i), copies of each U.S. Patent and each U.S. Patent Application Publication are not required to be submitted. Copies of any foreign patent documents and non-patent literature cited herein are enclosed.

☐ Each item of information contained in this Information Disclosure Statement was cited in the communication from a foreign patent office in a counterpart application, and the communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of this Information Disclosure Statement 37 C.F.R. § 1.704(d).

☐ Applicant submits that no fee is required for the consideration of this Information Disclosure Statement. However, if a fee is due, the Commissioner is hereby authorized to charge Deposit Account No 500252 referencing case number .
Consideration of the listed references and favorable action are solicited.

Respectfully submitted,



Jeff Landes, Esq.
Registration No.: 55,355
Isis Pharmaceuticals, Inc.
1896 Rutherford Road
Carlsbad, CA 92008

Dated: 2/20/2007

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**INFORMATION DISCLOSURE
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Sheet 1 of 11

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Application Number	10/660,997
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Attorney Docket Number	DIBIS-0002US.P2

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
	CQ	US-5,484,908	01-16-1996	Froehler et al.	
	CR	US-5,502,177	03-26-1996	Matteucci et al.	
	CS	US-5,503,980	04-02-1996	Cantor	
	CT	US-5,523,217	06-04-1996	Lupski et al.	
	CU	US-5,527,675	06-18-1996	Coull et al.	
	CV	US-5,567,587	10-22-1996	Kohne	
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		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
	DL	DE19802905	07-29-1999	Bruker Daltonik		
	DM	DE19824280	12-02-1999	Bruker Daltonik		
	DN	DE19852167	05-31-2000	Bruker Saxonia		
	DO	EP1138782	10-14-2001	Bruker Saxonia		
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	DU	WO 94/16101	07-21-1994	Koster		

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Application Number	10/660,997
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First Named Inventor	David J. Ecker
Art Unit	1637
Examiner Name	Jeffrey Norman Fredman
Attorney Docket Number	DIBIS-0002US.P2

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		Country Code ⁵ - Number ⁴ - Kind Code ⁵ (if known)				
	EP	WO 94/21822	09-24-1994	Koster		
	EQ	WO 96/29431	09-26-1996	Sequenom		
	ER	WO 96/32504	10-17-1996	Trust. of Boston		
	ES	WO 96/37630	11-28-1996	SRI International		
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	EW	WO 98/20020	05-14-1998	Sequenom Inc.		
	EX	WO 98/20157	05-14-1998	Infectio Diagnost.		
	EY	WO 98/26095	06-18-1998	Genetrace Sys.		
	EZ	WO 98/31830	07-23-1998	Brax Genomics		

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First Named Inventor	David J. Ecker
Art Unit	1637
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Attorney Docket Number	DIBIS-0002US.P2

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	FB	US-6,218,118	04-17-2001	Sampson et al.	
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	FU	WO 98/40520	09-17-1998	Hybridon Inc.		
	FV	WO 99/05319	02-04-1999	Rapigene, Inc.		
	FW	WO 99/29898	06-17-1999	Max-Planck		
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	GD	WO 02/10186	02-07-2002	California Instit.		

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		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
	GY	WO 02/18641	03-07-2002	Sequenom-Gemini		
	GZ	WO 02/21108	03-14-2002	Large Scale		
	HA	WO 02/50307	06-27-2002	Chugai Seiyaku		
	HB	WO 02/57491	07-25-2002	Board of Trustees of the Leland		
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	HD	WO 02/099034	12-12-2002	Infection Diagnostic		
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	HF	WO 03/008636	01-30-2003	Infectio Diagnost.		
	HG	WO 03/016546	02-27-2003	Flinders Technol.		
	HH	WO 03/060163	07-24-2003	Keygene N.V.		

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	HJ	US-6,605,433	08-12-2003	Fliss et al.	
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	HL	US-6,468,743	10-22-2002	Romick et al.	
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	HN	US-6,716,634	04-06-2004	Myerson	
	HO	US-2002/0045178	04-18-2002	Cantor et al.	
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	II	WO 03/088979	10-30-2003	Centre National		
	IJ	WO 03/097869	11-27-2003	Con/Cipio GmbH		

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	IK	BAHRMAND, A. R. et al., "Use of restriction enzyme analysis of amplified DNA coding for the hsp65 gene and polymerase chain reaction with universal primer for rapid differentiation of mycobacterium species in the clinical laboratory," <i>Scand. J. Infect. Diseases</i> (1998) 30(5):477-80.	
	IL	BAHRMAND, A. R. et al., "Polymerase chain reaction of bacterial genomes with single universal primer: application to distinguishing mycobacteria species," <i>Mol. Cell. Probes</i> (1996) 10(2):117-122.	
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	IN	BOIVIN-JAHNS, V. et al., "Bacterial Diversity in a Deep-Subsurface Clay Environment," <i>Appl. Environ. Microbiol.</i> (1996) 62(9):3405-3412.	
	IO	BOWEN, J. E. et al., "The native virulence plasmid combination affects the segregational stability of a theta-replicating shuttle vector in <i>Bacillus anthracis</i> var. New Hampshire," <i>J Appl Microbiol.</i> (1999) 87(2):270-278.	
	IP	CESPEDES, A. et al., "Polymerase chain reaction restriction fragment length polymorphism analysis of a short fragment of the cytochrome b gene for identification of flatfish species," <i>J. Food Protection</i> (1998) 61(12):1684-1685.	
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 7 of 11

Complete if Known

Application Number	10/660,997
Filing Date	09/12/2003
First Named Inventor	David J. Ecker
Art Unit	1637
Examiner Name	Jeffrey Norman Fredman
Attorney Docket Number	DIBIS-0002US.P2

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	IW	DIAS NETO, E. et al., "Shotgun sequencing of the human transcriptome with ORF expressed sequence tags," <i>PNAS</i> (2000) 97(7):3491-3496.	
	IX	DINAUER, D. M. et al., "Sequence-based typing of HLA class II DQB1," <i>Tissue Antigens</i> (2000) 55(4):364-368.	
	IY	DUBERNET, S. et al., "A PCR-based method for identification of Lactobacilli at the genus level," <i>FEMS Microbiology Letters</i> (2002) 214(2):271-275.	
	IZ	FIGUEIREDO, L. T. M. et al., "Identification of Brazilian flaviviruses by a simplified reverse transcription-polymerase chain reaction method using Flavivirus universal primers," <i>American Journal of Tropical Medicine and Hygiene</i> (1998) 59(3):357-362.	
	JA	FOX, A. et al., "Identification and detection of bacteria: electrospray MS-MS versus derivatization/GC-MS," <i>Proceedings of the ERDEC Scientific Conference on Chemical and Biological Defense Research</i> (1994) Aberdeen Proving Ground, Md., Nov. 15-18, p. 39-44.	
	JB	FUJIOKA, S. et al., "Analysis of enterovirus genotypes using single-strand conformation polymorphisms of polymerase chain reaction products," <i>J. Virol. Meth.</i> (1995) 51:253-258.	
	JC	GATTERMANN, N. et al., "Heteroplasmic Point Mutations of Mitochondrial DNA Affecting Subunit I of Cytochrome c Oxidase in Two Patients with Acquired Idiopathic Sideroblastic Anemia," <i>Blood</i> (1997) 90(12):4961-4972.	
	JD	GRIFFIN, T. J. et al., "Single-nucleotide polymorphism analysis by MALDI-TOF mass spectrometry," <i>Trends in Biotechnology</i> (2000) 18(2):77-84.	
	JE	HAHNER, S. et al., "Analysis of short tandem repeat polymorphisms by electrospray ion trap mass spectrometry," <i>Nucleic Acids Res.</i> (2000) 28(18):E82.	
	JF	HANNIS, J. C. et al., "Genotyping complex short tandem repeats using electrospray ionization Fourier transform ion cyclotron resonance multistage mass spectrometry," <i>Proceedings of SPIE-The International Society for Optical Engineering</i> (2000) 3926:36-47.	
*	JG	HAUGLAND, R. A. et al., "Identification of putative sequence specific PCR primers for detection of the toxigenic fungal species <i>Stachybotrys chartarum</i> ," <i>Mol. Cell. Probes</i> (1998) 12(6):387-396.	
	IH	HENCHAL, E. A. et al., "Sensitivity and specificity of a universal primer set for the rapid diagnosis of dengue virus infections by polymerase chain reaction and nucleic acid hybridization," <i>American Journal of Tropical Medicine and Hygiene</i> (1991) 45(4):418-428.	

* Copy of this reference is not being forwarded to the U.S. Patent and Trademark Office and is easily obtainable by the Examiner as it was cited in 10/660,996 Office Action dated 02/28/2006.

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**INFORMATION DISCLOSURE
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Sheet **B** of **11****Complete if Known**

Application Number	10/660,997
Filing Date	09/12/2003
First Named Inventor	David J. Ecker
Art Unit	1637
Examiner Name	Jeffrey Norman Fredman
Attorney Docket Number	DIBIS-0002US.P2

NON PATENT LITERATURE DOCUMENTS

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	JH	HERRMANN, B. et al., "Differentiation of <i>Chlamydia</i> spp. by Sequence Determination and Restriction Endonuclease Cleavage of RNase P RNA Genes," <i>J. Clin. Microbiol.</i> (1996) 34(8): 1897-1902.	
	JJ	HIGGINS, G. S. et al., "Competitive oligonucleotide single-base extension combined with mass spectrometric detection for mutation screening," <i>BioTechniques</i> (1997) 23(4):710-714.	
	JK	HONDA, K. et al., "Universal method of hypersensitive nested PCR toward forensic DNA typing," <i>International Congress Series</i> (1998) 7:28-30.	
	JL	HURST, G. B. et al., "MALDI-TOF analysis of polymerase chain reaction products from methanotrophic bacteria," <i>Anal. Chem.</i> (1998) 70(13):2693-2698.	
	JM	JOHNSON, Y. A. et al., "Precise molecular weight determination of CPR products of the rRNA intergenic spacer region using electrospray quadrupole mass spectrometry for differentiation of <i>B. subtilis</i> and <i>B. atrophaeus</i> , closely related species of bacilli," <i>J. Microbiol. Methods</i> (2000) 40(3):241-254.	
	JN	JURINKE, C. et al., "Detection of hepatitis B virus DNA in serum samples via nested PCR and MALDI-TOF mass spectrometry," <i>Genetic Analysis: Biomolecular Engineering</i> (1996) 13:67-71.	
	JO	KILPATRICK, D. R. et al., "Group-Specific Identification of Polioviruses by PCR Using Primers Containing Mixed-Base or Deoxyinosine Residues at Positions of Codon Degeneracy," <i>J. Clin. Microbiol.</i> (1996) 34(12):2990-2996.	
	JP	KRAHMER, M. T. et al., "Electrospray quadrupole mass spectrometry analysis of model oligonucleotides and polymerase chain reaction products: determination of base substitutions, nucleotide additions/deletions, and chemical modifications," <i>Anal. Chem.</i> (1999) 71(14):2893-2900.	
	JQ	KRAHMER, M. T. et al., "MS for identification of single nucleotide polymorphisms and MS/MS for discrimination of isomeric PCR products," <i>Anal. Chem.</i> (2000) 72(17):4033-4040.	
	JR	LACROIX, J.-M. et al., "PCR-based technique for the detection of bacteria in semen and urine," <i>J. Microbiol. Methods</i> (1996) 26:61-71.	
	JS	LEIF, H. et al., "Isolation and characterization of the proton-translocating NADH: ubiquinone oxidoreductase from <i>Escherichia coli</i> ," <i>Eur. J. Biochem.</i> (1995) 230(2):538-548.	
	JT	LI, J. et al., "Single nucleotide polymorphism determination using primer extension and time-of-flight mass spectrometry," <i>Electrophoresis</i> (1999) 20(6):1258-1265.	

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Sheet 9 of 11

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Application Number	10/660,997
Filing Date	09/12/2003
First Named Inventor	David J. Ecker
Art Unit	1637
Examiner Name	Jeffrey Norman Fredman
Attorney Docket Number	DIBIS-0002US.P2

NON PATENT LITERATURE DOCUMENTS

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	JU	LIU, Y. et al., "An unusual gene arrangement for the putative chromosome replication origin and circadian expression of <i>dnaN</i> in <i>Synechococcus</i> sp. strain PCC 7942," <i>Gene</i> (1996) 172(1):105-109.	
	JV	LOAKES, D. et al., "Nitroindoles as Universal Bases," <i>Nucleosides Nucleotides</i> (1995) 14:1001-1003.	
	JW	LOVE, B. C. et al., "Cloning and sequence of the <i>groESL</i> heat-shock operon of <i>Pasteurella multocida</i> ," <i>Gene</i> (1995) 166(1):179-180.	
	JX	MAIWALD, M. et al., "Characterization of contaminating DNA in Taq polymerase which occurs during amplification with a primer set for <i>Legionella</i> 5S ribosomal RNA," <i>Mol. Cell. Probes</i> (1994) 8(1):11-14.	
	JY	MARTEMYANOV, K. A. et al., "Extremely Thermostable Elongation Factor G from <i>Aquifex aeolicus</i> : Cloning, Expression, Purification, and Characterization in a Heterologous Translation System," <i>Protein Expr. Purif.</i> (2000) 18(3):257-261.	
	JA	MATRAY, T. J. et al., "Synthesis and properties of RNA analogs - oligoribonucleotide N3'→P5' phosphoramidates," <i>Nucleic Acids Res.</i> (1999) 27(20):3976-3985.	
	KA	MESSMER, T. O. et al., "Discrimination of <i>Streptococcus pneumoniae</i> from other upper respiratory tract streptococci by arbitrarily primed PCR," <i>Clin. Biochem.</i> (1995) 28(6):567-572.	
	KB	MORSE, R. et al., "Nucleotide Sequence of Part of the <i>ropC</i> Gene Encoding the β' Subunit of DNA-Dependent RNA Polymerase from some Gram-Positive Bacteria and Comparative Amino Acid Sequence Analysis," <i>System Appl. Microbiol.</i> (1996) 19:150-157.	
	KC	MUDDIMAN, D. C. et al., "Application of secondary ion and matrix-assisted laser desorption-ionization time-of-flight mass spectrometry for the quantitative analysis of biological molecules," <i>Mass Spectrometry Reviews</i> (1996) 14(6):383-429.	
	KD	MUDDIMAN, D. C. et al., "Important aspects concerning the quantification of biomolecules by time-of-flight secondary-ion mass spectrometry," <i>Applied Spectroscopy</i> (1996) 50(2):161-166.	
	KE	MUHAMMAD, W. T. et al., "Electrospray ionization quadrupole time-of-flight mass spectrometry and quadrupole mass spectrometry for genotyping single nucleotide substitutions in intact polymerase chain reaction products in K-ras and p53," <i>Rapid Commun. Mass Spectrom.</i> (2002) 16(24):2278-2285.	
	KF	MUSHEGIAN, A. R. et al., "A minimal gene set for cellular life derived by comparison of complete bacterial genomes," <i>Proc. Natl. Acad. Sci. USA</i> (1996) 93(19):10268-10273.	

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**INFORMATION DISCLOSURE
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Sheet 10 of 11

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Application Number	10/660,997
Filing Date	09/12/2003
First Named Inventor	David J. Ecker
Art Unit	1637
Examiner Name	Jeffrey Norman Fredman
Attorney Docket Number	DIBIS-0002US.P2

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	KG	REID, S. M. et al., "Primary diagnosis of foot-and-mouth disease by reverse transcription polymerase chain reaction," <i>Journal of Virological Methods</i> (2000) 89(1-2):167-176.	
	KH	REILLY, K. et al., "Design and use of 16S ribosomal DNA-directed primers in competitive PCRs to enumerate proteolytic bacteria in the rumen," <i>Microbiol. Ecol.</i> (2002) 43(2):259-270.	
	KI	ROSS, P. L. et al., "Analysis of DNA fragments from conventional and microfabricated PCR devices using delayed extraction MALDI-TOF mass spectrometry," <i>Anal. Chem.</i> (1998) 70(10):2067-2073.	
	KJ	SALA, M. et al., "Ambiguous base pairing of the purine analogue 1-(2-deoxy-β-D-ribofuranosyl)-imidazole-4-carboxamide during PCR," <i>Nucleic Acids Res.</i> (1996) 24(17):3302-6.	
	KK	SAUER, S. et al., "A novel procedure for efficient genotyping of single nucleotide polymorphisms," <i>Nucleic Acids Res.</i> (2000) 28(5):E13.	
	KL	SCHRAM, K. H., "Mass Spectrometry of Nucleic Acid Components," <i>Biomedical Applications of Mass Spectrometry</i> (1990) 34:203-280.	
	KM	SCHULTZ, J. C. et al., "Polymerase chain reaction products analyzed by charge detection mass spectrometry," <i>Rapid Communications in Mass Spectrometry</i> (1999) 13(1):15-20.	
	KN	SESHADRI, R. et al., "Differential Expression of Translational Elements by Life Cycle Variants of <i>Coxiella burnetii</i> ," <i>Infect. Immun.</i> (1999) 67(11):6026-6033.	
	KO	SHAVER, Y. J. et al., "Variation in 16S-23S rRNA intergenic spacer regions among <i>Bacillus subtilis</i> 168 isolates," <i>Molecular Microbiology</i> (2001) 42(1):101-109.	
	KP	TAKAHASHI, H. et al., "Characterization of <i>gyrA</i> , <i>gyrB</i> , <i>griA</i> and <i>griB</i> mutations in fluoroquinolone-resistant clinical isolates of <i>Staphylococcus aureus</i> ," <i>J. Antimicrob. Chemother.</i> (1998) 41(1):49-57.	
	KQ	TONG, J. et al., "Ligation reaction specificities of an NAD ⁺ -dependent DNA ligase from the hyperthermophile <i>Aquifex aeolicus</i> ," <i>Nucleic Acids Res.</i> (2000) 28(6):1447-1454.	
	KR	VAN AERSCHOT, A. et al., "In search of acyclic analogues as universal nucleosides in degenerate probes," <i>Nucleosides & Nucleotides</i> (1995) 14(3-5):1053-1056.	
	KS	VAN BAAR, B. L., "Characterisation of bacteria by matrix-assisted laser desorption/ionisation and electrospray mass spectrometry," <i>FEMS Microbiol. Rev.</i> (2000) 24(2):193-219.	

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Sheet 11 of 11

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Application Number	10/660,997
Filing Date	09/12/2003
First Named Inventor	David J. Ecker
Art Unit	1637
Examiner Name	Jeffrey Norman Fredman
Attorney Docket Number	DIBIS-0002US.P2

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	KT	VAN CAMP, G. et al., "Amplification and sequencing of variable regions in bacterial 23S ribosomal RNA genes with conserved primer sequences," <i>Curr. Microbiol.</i> (1993) 27(3):147-151.	
	KU	VAN DER VOSSEN, J. M. B. M. et al., "DNA based typing, identification and detection systems for food spoilage microorganisms: development and implementation," <i>Int. J. Food Microbiol.</i> (1996) 33(1):35-49.	
	KV	VAN ERT, M. N. et al., "Mass spectrometry provides accurate characterization of two genetic marker types in <i>Bacillus anthracis</i> ," <i>Biotechniques</i> (2004) 37(4):642-651.	
	KW	WALTERS, J. J. et al., "Genotyping single nucleotide polymorphisms using intact polymerase chain reaction products by electrospray quadrupole mass spectrometry," <i>Rapid Commun. Mass Spectrom.</i> (2001) 15(18):1752-1759.	
	KX	WELHAM, K. J. et al., "The Characterization of Micro-organisms by Matrix-assisted Laser Desorption/Ionization Time-of-flight Mass Spectrometry," <i>Rapid Commun. Mass Spec.</i> (1988) 12:176-180.	
	KY	WIDJOJOATMODJO, M. N. et al., "Rapid identification of bacteria by PCR-single-strand conformation polymorphism," <i>J. Clin. Microbiol.</i> (1994) 32(12):3002-3007.	
	KZ	WOLTER, A. et al., "Negative Ion FAB Mass Spectrometric Analysis of Non-Charged Key Intermediates in Oligonucleotide Synthesis: Rapid Identification of Partially Protected Dinucleoside Monophosphates," <i>Biomed. Environ. Mass Spectrom.</i> (1987) 14:111-116.	
	LA	WOO, T. H. S. et al., "Identification of <i>Leptospira inadai</i> by continuous monitoring of fluorescence during rapid cycle PCR," <i>Systematic and Applied Microbiology</i> (1998) 21(1):89-96.	
	LB	WUNSCHER, D. et al., "Discrimination among the <i>B. cereus</i> group, in comparison to <i>B. subtilis</i> , by structural carbohydrate profiles and ribosomal RNA spacer region PCR," <i>Systematic and Applied Microbiology</i> (1995) 17(4):625-635.	
	LC	WUNSCHER, D. S. et al., "Analysis of double-stranded polymerase chain reaction products from the <i>Bacillus cereus</i> group by electrospray ionization Fourier transform ion cyclotron resonance mass spectrometry," <i>Rapid Communications in Mass Spectrometry</i> (1996) 10(1):29-35.	
	LD	YAO, Z.-P. et al., "Mass Spectrometry-Based Proteolytic Mapping for Rapid Virus Identification," <i>Anal. Chem.</i> (2002) 74(11):2529-2534.	
	LE	YASUI, T. et al., "A specific oligonucleotide primer for the rapid detection of <i>Lactobacillus lindneri</i> by polymerase chain reaction," <i>Can. J. Microbiol.</i> (1997) 43(2):157-163.	
	LF	BLAST Search results (03/2006)	

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/156,608	05/24/2002	David J. Ecker	IBIS-0415	4995
58057	7590	06/02/2006	EXAMINER	
MEDLEN & CARROLL LLP 101 HOWARD STREET SUITE 350 SAN FRANCISCO, CA 94105			FREDMAN, JEFFREY NORMAN	
			ART UNIT	PAPER NUMBER
			1637	

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
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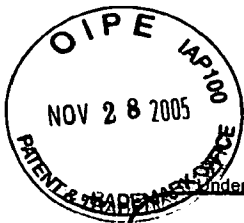
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Commissioner for Patents

The IDS filed May 23, 2005 was considered. The IDS filed November 28, 2005 was not considered but is placed in the application file.

Jeffrey Fredman
Primary Examiner
Art Unit: 1637

5/9/06



B

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1645

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Application Number	10/156,608
Filing Date	May 24, 2002
First Named Inventor	David J. Ecker
Art Unit	1645
Examiner Name	Jeffrey Fredman
Attorney Docket Number	DIBIS-0002US.D1

ENCLOSURES (Check all that apply)

- | | | |
|--|--|--|
| <input checked="" type="checkbox"/> Fee Transmittal Form
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<input type="checkbox"/> Terminal Disclaimer
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<input type="checkbox"/> CD, Number of CD(s) _____
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(Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Status Letter
<input checked="" type="checkbox"/> Other Enclosure(s) (please identify
below): |
|--|--|--|

Remarks
References

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name Isis Pharmaceuticals, Inc.

Signature

Printed name Mark P. Roach, Ph.D.

Date 11-22-05

Reg. No. L0082

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

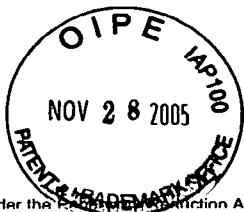
Signature

Typed or printed name Pamela Grooms

Date 11/22/05

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PTO/SB/17 (12-04)

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Effective on 12/08/2004.

Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL
For FY 2005☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$)

Complete if Known

Application Number	10/156,608
Filing Date	May 24, 2002
First Named Inventor	David J. Ecker
Examiner Name	Jeffrey Fredman
Art Unit	1645
Attorney Docket No.	DIBIS-0002US.D1

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☒ Deposit Account Deposit Account Number: 50-0252 Deposit Account Name: Isis Pharmaceuticals, Inc.

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, except for the filing fee

☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☐ Credit any overpayments

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**FEE CALCULATION****1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee (\$)	Small Entity Fee (\$)
Each claim over 20 or, for Reissues, each claim over 20 and more than in the original patent	50	25
Each independent claim over 3 or, for Reissues, each independent claim more than in the original patent	200	100
Multiple dependent claims	360	180

Total Claims	Extra Claims	Fee (\$)	Fee Paid (\$)	Multiple Dependent Claims	Fee (\$)	Fee Paid (\$)
- 20 or HP = _____ x _____ = _____						
HP = highest number of total claims paid for, if greater than 20						
Indep. Claims	Extra Claims	Fee (\$)	Fee Paid (\$)			
- 3 or HP = _____ x _____ = _____						
HP = highest number of independent claims paid for, if greater than 3						

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
- 100 = _____ / 50 = _____ (round up to a whole number) x _____ = _____				

4. OTHER FEE(S)

Non-English Specification, \$130 fee (no small entity discount)

Other: IDS Submission

130.00

SUBMITTED BY

Signature		Registration No. L0082 (Attorney/Agent)	Telephone (760) 931-9200
Name (Print/Type)	Mark P. Roach, Ph.D.	Date	11/22/2005

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NUMBER: 10/156,608
FILING DATE: May 24, 2002
FIRST NAMED INVENTOR: David J. Ecker
ART UNIT: 1645
EXAMINER NAME: Jeffrey Fredman
ATTORNEY DOCKET NUMBER: DIBIS-0002US.D1
TITLE:

I certify that this communication is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Dated: 11-22-05 By: Pamela Grooms
Pamela Grooms

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INFORMATION DISCLOSURE STATEMENT

Under 37 C.F.R. §§ 1.56 and 1.97-98

SIR:

Pursuant to the provisions of 37 C.F.R. §§ 1.56 and 1.97-98, enclosed herewith is PTO Form PTO/SB/08A and PTO/SB/08B listing references for consideration by the Examiner.

The filing of this Information Disclosure Statement shall not be construed as a representation regarding the completeness of the list of references, or that inclusion of a reference in this list is an admission that it is prior art or is pertinent to this application, or that a search has been made, or as an admission that the information listed is, or may be considered to be, material to patentability, or that no other material information exists, and shall not be construed as an admission against interest in any manner.

This Information Disclosure Statement is being filed:

☐ within three months of the filing date of the application, or date of entry into the national stage of an international application, or before the mailing date of a first office action on the merits, whichever event last occurred;

☐ before the mailing of a first official action after filing of a request for continued examination (RCE) under 37 C.F.R. § 1.114;

☐ after three months of the filing date of this national application or the date of entry of the national stage in an international application, or after the mailing date of the first official action on the merits, whichever event last occurred, but before that mailing date of the first office action to occur of either: (1) a final action under 37 C.F.R. § 1.113; or (2) an action that otherwise closes prosecution in the application, and:

☐ attached hereto is the fee set forth under 37 C.F.R. § 1.17(p) for submission of this Information Disclosure Statement under 37 C.F.R. § 1.97(c); OR

☐ Applicant certifies pursuant to 37 C.F.R. § 1.97(e) that:

☐ each item of the information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement;

OR

☐ no item of information contained in this Information Disclosure Statement was cited in a counterpart foreign application and, to the knowledge of the person signing this certification after making reasonable inquiry, no item of information contained in this Statement was known to any individual designated under 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Statement.

☐ on or before the payment of the issue fee but after the mailing date of the first to occur of either: (1) a final action under 37 C.F.R. § 1.113; (2) a notice of allowance under 37 C.F.R. § 1.311; or (3) an action that otherwise closes prosecution in the application, and:

☐ Applicant certifies pursuant to 37 C.F.R. § 1.97(e) that:

☐ each item of information contained in this Information Disclosure Statement was cited in a communication from a

foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement;

OR

☐ no item of information contained in this Information Disclosure Statement was cited in a counterpart foreign application and, to the knowledge of the person signing this certification after making reasonable inquiry, no item of information contained in this Statement was known to any individual designated under 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Statement. AND

☐ attached hereto is the fee set forth under 37 C.F.R. § 1.17(p) for submission of this Information Disclosure Statement under 37 C.F.R. § 1.97(c); OR

☒ after the payment of the issue fee. Applicant requests that the information contained in this Information Disclosure Statement be placed in the file according to 37 C.F.R. § 1.97(i), although the information may not be considered by the USPTO.

☒ Enclosed is a copy of each listed reference that may be material to the examination of this application, and for which there may be a duty to disclose.

☐ This application relies, under 35 U.S.C. § 120, on the earlier filing date of prior application No. , filed on , and the references cited therein are hereby referenced, but are not required to be provided in this application under 37 C.F.R. § 1.98(d).

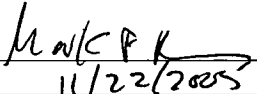
☐ This application was filed after June 30, 2003. Therefore, pursuant to the waiver of the requirements under 37 C.F.R. § 1.98(a)(2)(i), copies of each U.S. Patent and each U.S. Patent Application Publication are not required to be submitted. Copies of any foreign patent documents and non-patent literature cited herein are enclosed.

☒ Each item of information contained in this Information Disclosure Statement was cited in the communication from a foreign patent office in a counterpart application, and the communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of this Information Disclosure Statement 37 C.F.R. § 1.704(d).

☐ Applicant submits that no fee is required for the consideration of this Information Disclosure Statement. However, if a fee is due, the Commissioner is hereby authorized to charge Deposit Account No 500252 referencing case number

Consideration of the listed references and favorable action are solicited.

Respectively Submitted,


Dated: 11/22/2005

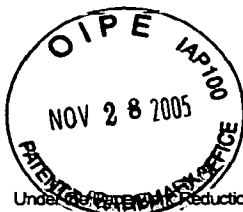
Mark P. Roach

Registration No.: **L0082**

Isis Pharmaceuticals, Inc.

1896 Rutherford Road

Carlsbad, CA 92008



PTO/SB/08b(08-03)

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known

Application Number	10/156,608
Filing Date	05/24/2002
First Named Inventor	David J. Ecker
Art Unit	1645
Examiner Name	Jeff Fredman
Attorney Docket Number	DIBIS-0002US.D1

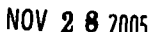
NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	AA	GRIFFIN, TIMOTHY J. et al., "Single-nucleotide polymorphism analysis by MALDI-TOF mass spectrometry," <i>Trends in Biotechnology</i> , (2000) 18(2): 77-84.	
	AB	HAHNER, S. et al., "Analysis of short tandem repeat polymorphisms by electrospray ion trap mass spectrometry," <i>Nucleic Acids Research</i> , (2000) 28(18): E82 (8 pgs.).	
	AC	JOHNSON, YEVETTE, A. et al., "Precise molecular weight determination of CPR products of the rRNA intergenic spacer region using electrospray quadrupole mass spectrometry for differentiation of <i>B. subtilis</i> and <i>B. atrophaeus</i> , closely related species of bacilli," <i>Journal of Microbiological Methods</i> , (2000) 40(3): 241-254.	
	AD	SAUER, SASCHA et al., "A novel procedure for efficient genotyping of single nucleotide polymorphisms," <i>Nucleic Acids Research</i> , (2000) 28(5): E13 (8 pgs.).	
	AE	VAN ERT, MATTHEW N. et al., "Mass spectrometry provides accurate characterization of two genetic marker types in <i>Bacillus anthracis</i> ," <i>Biotechniques</i> (2004) 37(4): 642-651.	

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



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Sheet

2

of

2

Complete if Known

Application Number

10/156.608

Filing Date

05/24/2002

First Named Inventor

David J. Ecker

Art Unit

1645

Examiner Name _____

Jeff Fredman

Attorney Docket Number

DIBIS-0002US.D1

U.S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

[illegible]

Examiner Signature		Date Considered	
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